

Confirmation No. 1188

PHA-01336 [PC27711A]

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : Robert M. Noack, et al.

EXAMINER : Unknown

SERIAL NO. : 10/816,699

ART UNIT : 1615

FILED : April 2, 2004

PAPER NO :

FOR : Oral Extended Release Compressed Tablets Of Multiparticulates

Statement as Provided by 37 CFR 1.97(b)

Commissioner for Patents  
P.O. BOX 1450  
Alexandria, VA 22313-1450

Dear Sir:

The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of the first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

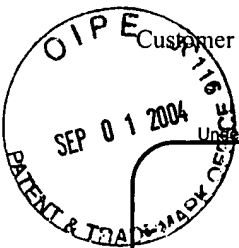
It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (MPEP § 1302.12).

It is understood by the Applicants that this paper requires no fee; however, authorization is given to charge any necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Respectfully submitted,

Dated: 8/30/04

Karen B. King  
Karen B. King  
Registration No. 41,898  
Warner-Lambert Company  
2800 Plymouth Road  
Ann Arbor, MI 48105  
Telephone: (734) 622-4837  
Facsimile: (734) 622-1553



Customer No. 28880

Confirmation No. 1188

PTO/SB/21 (03-03)

Approved for use through 04/30/2003. OMB 0651-0031

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Application Number	10/816,699
Filing Date	April 2, 2004
First Named Inventor	Robert M. Noack et al
Art Unit	1615
Examiner Name	
Attorney Docket Number	PHA-01336 [PC27711A]

Total Number of Pages in This Submission

**ENCLOSURES (Check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input checked="" type="checkbox"/> Response to Missing Parts/ Incomplete Application <input checked="" type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to a Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): Statement as Provided by 37 CFR 1.97(b) Return Post Card
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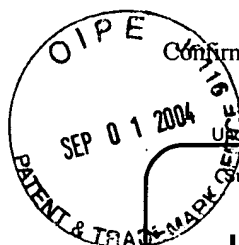
Firm or Individual	Karen B. King
Signature	<i>Karen King</i>
Date	8/30/04

**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date <u>8/30/04</u>		
Typed or printed	Linda Zerby	
Signature	<i>Linda L. Zerby</i>	Date <u>8/30/04</u>

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/816,699
Filing Date	April 2, 2004
First Named Inventor	Robert M. Noack et al
Art Unit	1615
Examiner Name	Unknown
Attorney Docket Number	PHA-01336 [PC27711A]

Sheet 1 of 2

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5260068	11-09-1993	Chih-Ming Chen, et al	
		US- 5260069	11-09-1993	Chih-Ming Chen, et al	
		US- 5484608	01-16-1996	Edward M. Rudnie, et al	
		US- 5780055	07-14-1998	Yacoub S. Habib, et al	
		US- 5945124	08-31-1999	George Sachs, et al	
		US- 6068856	05-30-2000	George Sachs, et al	
		US- 6132768	10-17-2000	George Sachs, et al	
		US- 6177101-B1	01-23-2001	Alice C. Martino, et al	
		US- 6224910-B1	05-01-2001	Ismat Ullah, et al	
		US- 6228398-B1	05-08-2001	John G. Devane, et al	
		US- 6248363-B1	06-19-2001	Mahesh V. Patel, et al	
		US- 6274173-B1	08-14-2001	George Sachs, et al	
		US- 6335033-B2	01-01-2002	Benjamin Oshlack, et al	
		US- 6340475-B2	01-22-2002	John W. Shell, et al	
		US- 6406745-B1	06-18-2002	James D. Talton, et al	
		US- 6517866-B1	02-11-2003	Mary Tanya Am Ende, et al	
		US- 2002/0012675-A1	01-31-2002	Rajeev A. Jain, et al	
		US- 2002/0015729-A1	02-07-2002	Patrea L. Pabst, et al	
		US- 2003/0026839-A1	02-06-2003	Benjamin Oshlack, et al	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		EP1027887-A2	08-16-2000	Leah Elizabeth Appel, et al		<input type="checkbox"/>
		WO 98/32427-A1	07-30-1998	Jean A Setterstrom, et al		<input type="checkbox"/>
		WO 00/18374-A1	04-06-2000	Jon Swanson, et al		<input type="checkbox"/>
		WO 00/69420-A1	11-23-2000	Yoseph Bornstein, et al		<input type="checkbox"/>
		WO 01/19345-A1	03-22-2001	Brita Sjoblom, et al		<input type="checkbox"/>
		WO 01/37808	05-31-2001	Manesh V. Patel, et al		<input type="checkbox"/>

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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US 10/816,699 FILED April 2, 2004  
Docket No. PHA-01336 [PC27711A]

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>		
				Application Number	10/816,699	
				Filing Date	April 2, 2004	
				First Named Inventor	Robert M. Noack et al	
				Art Unit	1615	
Examiner Name	Unknown					
Attorney Docket Number	PHA-01336 [PC27711A]					
Sheet	2	of	2			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		E. A. HOSNY, et al., "Formulation and In Vitro and In Vivo Availability of Diclofenac Sodium Enteric-Coated Beads", Drug Development and Industrial Pharmacy, 1998, Vol. 24, No., 7, pp 661-666	
		S. Y. LIN, et al., "Micronized Ethylcellulose Used for Designing a Directly Compressed Time-Controlled Disintegration Tablet", Journal of Controlled Release, 2001, Vol. 70, pp 321-328	
		D. MAZUR, et al., "Bioavailability and Selected Pharmacokinetic Parameters of Clindamycin Hydrochloride After Administration of a New 600 mg Tablet Formulation", International Journal of Clinical Pharmacology and Therapeutics, 1999, Vol. 37, No. 8, pp 386-392	
		A OSOL, et al., Remington's Pharmaceutical Sciences, 16th Edition, 1980, pp 1245-1248	
		J. P. REO, et al., "Taste Masking Science and Technology Applied to Compacted Oral Solid Dosage Forms - Part 3", American Pharmaceutical Review, 2002, Vol. 4, pp 1-6	
		A. J. RIBEIRO, et al., "Microencapsulation of Lipophilic Drugs in Chitosan-coated Alginate Microspheres", International Journal of Pharmaceutics, 1999, Vol. 187, pp 115-123	
		M. RODRIGUEZ, et al., "Design of a New Multiparticulate System for Potential Site-Specific and Controlled Drug Delivery to the Colonic Region", Journal of Controlled Release, 1998, Vol. 55, pp 67-77	
		T. YAO, et al., "Tableting of Coated Particles. I. Small Particle Size Chitosan as an Agent Protecting Coating membrane from Mechanical Damage of Compression Force", Chemical and Pharmaceutical Bulletin, 1997, Vol. 45, No. 9 pp 1510-1514	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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